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09/143,379 08/28/98 KOGANTY R 042881/0119

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EXAMINER

WESSENDORF, T

ART UNIT

PAPER NUMBER

1618

DATE MAILED:

12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/143,379

Applicant(s)

Gandhi et al

Examiner

T. Wessendorf

Group Art Unit

1618



☒ Responsive to communication(s) filed on Sep 17, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-41 is/are pending in the application

Of the above, claim(s) 1-31, 39, and 41 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 32-38 and 40 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The specification is objected to because of syntax errors e.g., "any step of then process" at page 7, line 11; "was purified by crystallized" at page 20, line 22.

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The drawings are objected to because 1). Figure 7 is not on file. 2). The specification describes only a Figure 3 but the drawings contain two figures for said Figure 3. Should applicants amend the drawing to show Fig. 3 as A and B, then the specification should reflect these changes.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicants' election of Group II, claims 32-41 and the species of peptide platforms and anti-bacterial compounds, claims 31, 33-38 and 40 in Paper No. 7 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Applicants stipulate that claims 31, 33-38 and 40 reads on the elected species. However, claim 31 is outside the elected group. Accordingly, the claims that read on the elected species are claims 32-38 and 40.

Claims 1-31, 39 and 41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention and species. Election was made **without** traverse in Paper No. 7.

Claims 32-38 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). It is not clear, within the claimed context, as to a randomly-generated library. Is the claim drawn to a random production of the library or that the library contains a random e.g., residues in some positions and a fixed residue on the other positions? Cf. with the recitation in the specification at e.g., page 9, line 20 wherein the library is a library of a random components e.g., a random carbohydrate residue attach to the core peptide as opposed to a fixed residue. Claims 32 and 33.

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B). Regarding claim 38, the phrase "drug-like" renders the claim indefinite because the scope of the claimed like is unascertainable. Also, claim 33 recitation of carcinoma-associated mucins. It is not clear in what respect the mucins are associated to carcinoma.

C). The term "platform" provides for confusion and ambiguity and appears to go against the conventional term of a core or scaffold e.g., peptide. (E.g., claim 34).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 32, 38 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Rao et al (5,795,958).

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The claimed randomly-generated glycopeptide library and method of screening said library for an anti-bacterial compound are fully met by the glycopeptide library and method of screening of Rao which describes a random glycopeptide library and method at e.g., col. 3, line 25 up to col. 5, line 53 and the Examples at col. 14, line 1 up to col. 21, line 49.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-37 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al.

The claimed library of glycosylated platforms produced by the different recited processes is anticipated or obvious over the specific glycopeptide library of Rao which describes a glycosylated platform i.e., peptide library at e.g., col. 3, line 25 up to col. 5, line 53 and the Examples at col. 14, line 1 up to col. 21, line 49. The claimed glycosylated platform library appears to be the same or similar to the prior art, absent a

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showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the libraries i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is upon the applicants to prove that the claimed library produced by the claimed process are different from those taught by the prior art and to establish patentable differences. See *In re Marosi*, 218 USPQ 282, 292-293 (CAFC 1983); *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

Claims 32 and 34-38 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vetter et al (WO 95/18971).

The broadly claimed randomly-generated glycopeptide library is anticipated or obvious over the glycopeptide library of Vetter. Also, a library of glycosylated platforms(i.e., peptide)using the glycosyl residue is disclosed by Vetter. See e.g., page 6, line 10 up to page 7, line 5; page 25, line 1 up to page 27, line 10 and page 34, lines 1-25. See *In re Marosi* or *In re Thorpe*, supra.

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Claims 32 and 34-38 are rejected under 35 U.S.C. 102(a) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schleyer et al (Angew. Chem. Int.)

The broadly claimed randomly-generated glycopeptide library is anticipated or obvious over the glycopeptide library of Schleyer. Furthermore, Schleyer discloses a library of glycosylated platforms(i.e., peptide)using the glycosyl residue at e.g., page 1976, col. 1. See In re Marosi or Thorpe, above.

Claims 32-37 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frische et al (abstract of J. Pept. Sci.)

The broadly claimed randomly-generated glycopeptide library is anticipated or obvious over the specific glycopeptide library i.e., a glycosylated peptide of Frische. Frische discloses a multiple synthesis of a series of random glycosyl incorporated into the peptide core. Thus, it is considered that the series of different glycopeptides produces a library of the same components. See the abstract. See In re Marosi or Thorpe, above.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Danishefsky discloses a strategy for the solid phase synthesis of oligosaccharides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

12/3/99

T. Wessendorf